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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,319

07/15/2005

Philippe A. Tessier

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EXAMINER

WEN, SHARON X

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

07/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,319	Applicant(s) TESSIER ET AL.	
	Examiner SHARON WEN	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 5 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/23/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment, filed 01/23/2008, has been entered.
Claims 2, 4, 6-13 have been canceled.
Claim 14 has been added.
Claims 1, 3, 5, and 14 are pending and currently under examination as they read on a method for inhibiting the recruitment of neutrophils causative of gout (as the elected disease) comprising administering an antibody against extracellular S100A8 protein and an antibody against extracellular S100A9 protein.
2. Text of those sections of Title 35 U.S.C. not included in this Action can be found in a prior Action.
This Action will be in response to Applicant's Arguments/Remarks, filed 01/23/2008.
The rejections of record can be found in the previous Office Action.

Information Disclosure Statement

3. Applicant's IDS, filed on 01/23/2008 are acknowledged, and have been considered.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1 and 5 stand rejected under 35 U.S.C. 102(e) as being anticipated by Hanash (US 2002/0192228 A1, reference of record, see entire document) as evidenced by Seto et al. (US Patent 6,706,683 B1, reference of record, see entire document).

Applicant's arguments, filed 01/23/2008, have been fully considered but have not been found convincing essentially for the reasons of record.

In response to Applicant's argument that the prior art does not teach the newly added claim limitation of causative role of S100A8 and S100A9 in inflammation, the following is noted:

Under the broadest reasonable interpretation of the claims 1 and 5, by meeting the active step of administering an antibody against extracellular S100A8 protein and an antibody against extracellular S100A9 protein to an individual would *necessarily* meet the preamble of the claims, i.e., "inhibiting the recruitment of neutrophils causative of an inflammatory reaction in a human individual".

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. Given that Hanash teaches the intravenous and subcutaneous administration of antibodies against S100A8 and S100A9 in a human (e.g., see paragraphs [0110]-[0112], [0115]-[0116], and [0125]), therefore, it would necessarily inhibit the recruitment of neutrophils causative of an inflammatory reaction in a human individual.

In response to the newly added "extracellular" limitation, the following is noted:

Given that Hanash teaches a polyclonal antibody against an antigen formed by heterodimerization of S100A8 and S100A9 that cross reacts with both proteins (see paragraph [0112] and [0125]), one of ordinary skill would have immediately recognized that the prior art polyclonal antibodies would comprise at least one antibody against extracellular S100A8 and at least one antibody against extracellular S100A9.

Since the Office does not have a laboratory to test the reference antibodies, it is Applicant's burden to show that the reference antibodies do not bind the extracellular S100A8 and A9.

Applicant's arguments have not been persuasive.

This rejection is **maintained**.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 3 and 5 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seto et al. (WO00/18970 published in Japanese) as evidenced by its English translation in US Patent 6,706,683 B1, reference of record, in view of Dinerstein et al (US Patent 5,248,825, reference of record) and Hanash (US 2002/0192228 A1, reference of record).

Applicant's arguments, filed 01/23/2008, have been fully considered but have not been found convincing essentially for the reasons of record.

Consistent with the above section, in response to Applicant's argument in the mechanism of the S100A8 and A9 protein in inflammation, it is noted that, under the broadest reasonable interpretation of the claim, by meeting the active step of administering an antibody against extracellular S100A8 protein and an antibody against extracellular S100A9 protein to an individual would *necessarily* meet the preamble of the claims, i.e., "inhibiting the recruitment of neutrophil causative of an inflammatory reaction in a human individual".

Given that Seto et al. teach using antibodies against S100A8 and S100A9 to inhibit activation of neutrophils and that Dinerstein et al. teach that neutrophils play integral part in the pathogenesis of gout, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to administer antibodies against S100A8 and S100A9 for treating gout.

Therefore, the invention, as a whole, was *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments have not been found persuasive.

This rejection is **maintained**.

Conclusion

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen, Ph.D./
Examiner, Art Unit 1644
July 21, 2008

/Phillip Gambel/
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